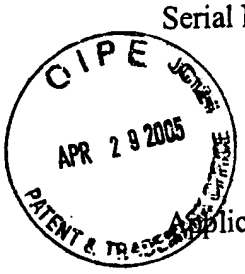
AF 3731



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Chandru Chandrasekaran

Appln No.: 10/075,914

Filed: February 14, 2002

Title: METAL REINFORCED BIODEGRADABLE INTRALUMINAL STENTS

Art Unit: 3731

Examiner: Sarah K. Webb

Confirmation No.: 1739

Docket No.: 01-462

Mail Stop Appeal Brief-Patents
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

PETITION FOR EXTENSION OF TIME UNDER 1.136(a) AND APPEAL BRIEF UNDER 37 C.F.R. §1.192

Sir:

Applicant hereby petitions the Assistant Commissioner to grant a one (1) month extension of time, up to and including April 27, 2005, in which to file the enclosed Appeal Brief in the above-identified application. The extension fee in the amount of $120.00 may be charged to deposit account No. 50-1047. In addition, the $500 fee for filing the Brief in support of the Appeal and any deficiencies may be charged to deposit account No. 50-1047.

As set forth in the Notice of Appeal filed by first-class mail on January 24, 2005, Appellants hereby appeal the final decision of the Examiner in the above-identified application rejecting claims 1-27, which are all of the pending claims in the application. Appellant respectfully requests that the Board of Patent Appeals and Interferences reverse the Examiner's rejection of the claimed subject matter.

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I. BRIEF ON APPEAL

This appeal is from the examiner's final rejection of September 24, 2004.

II. REAL PARTY IN INTEREST

Scimed Life Systems, Inc. is the assignee of the present invention and the real party in interest.

III. RELATED APPEALS AND INTERFERENCES

No other appeals or interferences within the meaning of 37 CFR 1.912(c) are known to Appellant, Appellant's legal representative, or the assignees, which will directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

IV. STATUS OF CLAIMS

The appeals claims in the application are claims 1-27, all of which currently stand rejected. The presently pending claims are provided in the attached Appendix.

Claims 14 and 16 stand finally rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

Claims 1-10, 13, 15, 18, 20-22, 25 and 27 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by Ragheb et al. U.S. Patent No. 5,824,049 (Ragheb).

Claims 1, 5-10 and 12-14 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by Wolff et al. U.S. Patent No. 5,725,567 (Wolff).

Claims 2 and 11 have been finally rejected under 35 U.S.C. §103(a) as being unpatentable over Wolff in view of Mayer U.S. Patent No. 5,630,840.

Claims 14, 16, 17, 19, 23, 24 and 26 have been finally rejected under 35 U.S.C. §103(a) as being unpatentable over Ragheb and Wolff taken together.

V. STATUS OF AMENDMENTS

A Final Office Action was mailed on September 24, 2004, rejecting Claims 1-27. An Amendment and Response was filed subsequent to the Final Office Action on November 23, 2004, and in an Advisory Action mailed on December 21, 2004, the Examiner indicated her refusal to enter the proposed Amendments to the claims that were filed on November 23, 2004. A Notice of Appeal was filed by first-class mail on January 24, 2005, and received by the Patent and Trademark Office on January 27, 2005.

VI. SUMMARY OF CLAIMED SUBJECT MATTER

The claim 1, the only independent claim as follows:

> 1. An intraluminal stent comprising:
>
> a metallic reinforcing component; and
>
> a biodegradable polymeric material covering at least a portion of the metallic reinforcing component;
>
> the metallic reinforcing component providing structural reinforcement for the stent but being insufficient, in the absence of the biodegradable polymeric material, to provide a stent capable of maintaining patency of a lumen upon implantation of the stent into the lumen.

The novel and unobvious improvement is recited in the final paragraph of the claim. The metallic reinforcing component differs from those previously used in that it has insufficient mechanical integrity, in the absence of the biodegradable polymeric material, to provide a stent capable of maintaining patency of a lumen upon implantation of the stent into the lumen.

As noted in paragraph [0031] of the present specification, in contrast to known composite stents, the here-claimed stent utilizes both the metallic component and the biodegradable polymeric component to provide the mechanical properties required to maintain the patency of the lumen upon implantation of the stent into a body lumen.

Advantages of the here-claimed stent are several. See paragraph [0034].

Because the metallic reinforcing component is not relied on as the sole source of

mechanical strength, a stent can be provided that advantageously utilizes less metal and more biodegradable polymeric material.

Metallic materials are often more rigid and less compliant than biodegradable materials. The relative rigidity of metallic materials can compromise the goal of providing a stent that is biomechanically compatible, i.e., compliant with the contacting lumen walls.

Because less metal is utilized in the here-claimed stent, thinner and more flexible metallic filaments or sheets can be utilized to provide a flexible metallic reinforcing component. Thus, upon *in vivo* biodegradation of the polymeric material, the remaining flexible metallic framework of the stent will be advantageously less bulky and have a smaller surface area in direct contact with the lumen walls. At such point, the remaining flexible metallic framework of the stent will be more compliant with the contacting lumen walls and be less likely to cause damage or injury to the same if left implanted indefinitely.

By appropriate selection of metallic and biodegradable polymeric materials, the present invention provides an enhanced ability to customize the mechanical properties of an intraluminal stent dependent, for example, on the time dependent changes associated with lumen healing or remodeling. See paragraph [0037].

VII. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 14 and 16 stand finally rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

Claims 1-10, 13, 15, 18, 20-22, 25 and 27 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by Ragheb et al. U.S. Patent No. 5,824,049 (Ragheb).

Claims 1, 5-10 and 12-14 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by Wolff et al. U.S. Patent No. 5,725,567 (Wolff).

Claims 2 and 11 have been finally rejected under 35 U.S.C. §103(a) as being unpatentable over Wolff in view of Mayer U.S. Patent No. 5,630,840.

Claims 14, 16, 17, 19, 23, 24 and 26 have been finally rejected under 35 U.S.C. §103(a) as being unpatentable over Ragheb and Wolff taken together.

VIII. ARGUMENT

The following legal authorities are relied on in the following argument in the order in which they are cited.

M.P.E.P. 2173.05(h)

Ex parte Levy, 17 U.S.P.Q2d 1461, 1464 (B.P.A.I. 1990)

In re Oelrich, 666 F.2d 578, 581, U.S.P.Q. 323, 326 (C.C.P.A. 1981)

In re Rijckaert, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993)

In re Swinehart, 439 F.2d 210, U.S.P.Q. 226, 228 (C.C.P.A. 1971)

In re Fuetterer, 319 F.2d 259, 138 U.S.P.Q. 217, 222 (C.C.P.A. 1963)

In re Baird, 29 U.S.P.Q.2d 1550, 1552 (Fed. Cir. 1994)

The references:

Ragheb: This reference discloses only that which was acknowledged as prior art. That is, metallic stents having a biodegradable polymeric coating, said coating being used for incorporating and proving localized release therefrom of a therapeutic agent.

Wolff: This reference teaches no more than the acknowledged prior art and is similar to Ragheb in that respect.

Mayer: This reference discloses only various metallic constructions but does not disclose any biodegradable polymer component.

The rejections:

A. Claims 14 and 16 have been rejected under the first paragraph of 35 U.S.C. §112 as being indefinite.

In the absence of Markush language, the examiner states that it is not clear "what is to be contained in the polymeric coating." No explanation for that position has been set forth. In the absence of such explanation, it is not apparent why the recitation "said biodegradable polymeric material coating layer comprises one or more therapeutic agents, one or more diagnostic agents, or a combination of one or more therapeutic agents and one or more diagnostic

agents" would not be definite to one of ordinary skill in the art reading the claim. Alternative and Markush forms are expressly set forth as equivalent in M.P.E.P. 2173.05(h). See paragraphs I and II.

Appellant attempted to add the Markush recitation suggested by the examiner simply to reduce the issues on appeal, but the amendment was refused entry.

B. Claims 1-10, 13, 15, 18, 20-22, 25 and 27 have been rejected under 35 U.S.C. §102(b) as being anticipated by Ragheb.

The novel and unobvious feature of the claimed invention discussed in Section VI above is not disclosed in this reference. See the description of Ragheb above. As stated earlier, the concept of using a biodegradable polymer coating over a metallic stent for supplying therapeutic agents is acknowledged prior art. The concept of the invention, in which a polymeric coating is used to provide structural support to a metallic stent that would otherwise not have sufficient strength to maintain patency of a lumen upon implantation of the stent into the lumen, however, is not in the prior art and is not disclosed in Ragheb. As also stated earlier, this is advantageous in that upon *in vivo* biodegradation of the polymeric material, the remaining flexible metallic framework of the stent will be less bulky, will have a smaller surface area in direct contact with the lumen walls, and will be more compliant with the contacting lumen walls.

In the final rejection, the examiner took the position, apparently, that the novel and unobvious feature of the claimed structure was inherent in the coated stents of Ragheb. There is, however, no evidence or clear explanation to support the examiner's conclusion. *Ex parte Levy*, 17 U.S.P.Q2d 1461, 1464 (B.P.A.I. 1990). A holding of inherency must flow as a necessary conclusion from the prior art, not simply a possible one. *In re Rijckaert*, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993), *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981).

Indeed, it is unlikely that the novel and unobvious feature of the invention at hand would have been found in any of the Ragheb constructions with no mention of the feature at all. Note that Ragheb teaches beginning with a metallic

structure known to be capable of use with no polymeric coating. See the paragraph bridging columns 6 and 7.

In the advisory action, the examiner stated that the novel and unobvious recitation of the appealed claims "is functional language directed toward intended use." There is no prohibition of the use of functional language to distinguish over the prior art, but in this case the controverted limitation actually describes a *property* of the claimed structure, not merely a *function*. See *In re Swinehart*, 439 F.2d 210, U.S.P.Q. 226, 228 (C.C.P.A. 1971).

On the issue of functional limitations generally, see *In re Fuetterer*, 319 F.2d 259, 169U.S.P.Q. 217, 222 (C.C.P.A. 1963).

C. Claims 1, 5-10, and 12-14 have been rejected under 35 U.S.C. §102(b) as being anticipated by Wolff.

Many of the same arguments applied to Ragheb are relevant to Wolff. The novel and unobvious feature of the claimed invention discussed in Section VI above is not disclosed in this reference, nor is the concept of the present invention disclosed. It is unlikely that the novel and unobvious feature of the invention would have been found in any of the Wolff constructions with no mention of the feature at all. Like Ragheb, Wolff teaches the use of metallic structures known to be capable of use with no polymeric coating. See, e.g., column 2, lines 9-18 and 32-38.

The examiner at one point relied on Figure 14 of Wolff and its description at column 7, lines 18-22, as showing bonding of the metallic component to the polymeric component. Actually the figure represents bonding of individual strands of metal to *each other* by melting the filament junctures at elevated temperatures. Column 7, lines 26-27. The reason for that bonding is that it "improves the radial strength," thus further indicating that the metallic component was intended to provide the structural strength required for the device and teaching away from appellant's improvement. See *In re Baird*, 29 U.S.P.Q.2d 1550, 1552 (Fed. Cir. 1994).

D. Claims 2 and 11 have been rejected under 35 U.S.C. §103(b) as being unpatentable over Wolff in view of Mayer.

Since Mayer relates only to metallic stents, as set forth above, and since Wolff neither discloses nor suggests the features or the concepts of the appealed claims, it follows *a fortiori* that the instant claims cannot be held to be obvious over the combinations of references relied on under 35 U.S.C. §103(a).

E. Claims 14, 16, 17, 19, 23, 24 and 26 have been rejected under 35 U.SC. §103(a) as being unpatentable over Ragheb and Wolff taken together.

Since neither Ragheb nor Wolff discloses or suggests the features or the concepts of the appealed claims, it follows that the instant claims can not be held to be obvious over the combinations of references relied on under 35 U.S.C. §103(a).

IX. CONCLUSION

None of the claims are indefinite. The references support no rejection under 35 U.S.C. §102 or §103. Thus, it is respectfully submitted that reversal of the rejections of record is in order.

X. FEES

The Office is authorized to charge the $500 fee for filing this brief in support of the Appeal, the $120 one-month extension fee and any additional fees due and owing in respect to the filing of this paper to deposit account number 50-1047.

Respectfully submitted,

David B. Bonham Reg. No. 34,297

Certificate of Mail

I hereby certify that this document is being deposited with the US Postal Service as first class mail under 37 C.F.R. 1.8 and addressed to: Mail Stop Appeal Brief – Patents; Commissioner for Patents; PO Box 1450; Alexandria, VA 22313-1450 on

4/27/2005

Marjorie Scariati

(Printed Name of Person Mailing Correspondence)

(Signature)

APPENDIX I. CLAIMS ON APPEAL

1. (Original) An intraluminal stent comprising:

a metallic reinforcing component; and

a biodegradable polymeric material covering at least a portion of the metallic reinforcing component;

the metallic reinforcing component providing structural reinforcement for the stent but being insufficient, in the absence of the biodegradable polymeric material, to provide a stent capable of maintaining patency of a lumen upon implantation of the stent into the lumen.

2. (Original) The intraluminal stent of claim 1, wherein the metallic reinforcing component comprises a biocompatible metal selected from the group consisting of stainless steel, titanium alloys, tantalum alloys, nickel alloys, cobalt alloys and precious metals.

3. (Original) The intraluminal stent of claim 2, wherein the biocompatible metal comprises a shape memory alloy.

4. (Original) The intraluminal stent of claim 3, wherein the shape memory alloy comprises a nickel-titanium alloy.

5. (Original) The intraluminal stent of claim 1, wherein the biodegradable polymeric material comprises a biocompatible biodegradable polymer selected from the group consisting of polylactic acid, polyglycolic acid, polycaprolactone, polyorthoesters, and trimethylene carbonate polymers, as well as copolymers and mixtures thereof.

6. (Original) The intraluminal stent of claim 1, wherein the stent is selected from the group consisting of endovascular, biliary, tracheal, gastrointestinal, urethral, ureteral and esophageal stents.

7. (Previously presented) The intraluminal stent of claim 6, wherein the stent is selected from the group consisting of a balloon-expandable stent and a self-expandable stent.

8. (Previously presented) The intraluminal stent of claim 6, wherein the stent is an endovascular stent.

9. (Original) The intraluminal stent of claim 1, wherein the metallic reinforcing component comprises a plurality of apertures.

10. (Previously presented) The intraluminal stent of claim 9, wherein the metallic reinforcing component is selected from the group consisting of an open-mesh network comprising one or more knitted, woven or braided metallic filaments; an interconnected network of articulable segments; a coiled or helical structure comprising one or more metallic filaments; and a patterned tubular metallic sheet.

11. (Previously presented) The intraluminal stent of claim 9, wherein the metallic reinforcing component is selected from the group consisting of an open-mesh network comprising one or more knitted, woven or braided metallic filaments and a coiled or helical structure comprising one or more metallic filaments, and wherein said metallic filaments comprise two or more different metals.

12. (Previously presented) The intraluminal stent of claim 9, wherein the metallic reinforcing component is a patterned tubular metallic sheet and wherein the patterned tubular metallic sheet is formed by laser cutting or chemical etching of a metallic sheet.

13. (Original) The intraluminal stent of claim 9, wherein the biodegradable polymeric material covering at least a portion of the metallic reinforcing component comprises a biodegradable polymeric material coating layer.

14. (Previously presented) The intraluminal stent of claim 13, wherein said biodegradable polymeric material coating layer comprises one or more therapeutic

agents, one or more diagnostic agents, or a combination of one or more therapeutic agents and one or more diagnostic agents.

15. (Original) The intraluminal stent of claim 9, wherein the biodegradable polymeric material covering at least a portion of the metallic reinforcing component comprises two or more biodegradable polymeric material coating layers.

16. (Previously presented) The intraluminal stent of claim 15, wherein one or more of the biodegradable polymeric material coating layers comprise one or more therapeutic agents, one or more diagnostic agents, or a combination of one or more therapeutic agents and one or more diagnostic agents.

17. (Previously presented) The intraluminal stent of claim 16, wherein different therapeutic agents or different combinations of therapeutic agents are present in two or more of said biodegradable polymeric material coating layers.

18. (Original) The intraluminal stent of claim 15, wherein at least two of said biodegradable polymeric material coating layers have different rates of biodegradation.

19. (Previously presented) The intraluminal stent of claim 16, wherein at least two of said biodegradable polymeric material coating layers comprise a therapeutic agent and have different rates of release of the therapeutic agent therefrom.

20. (Original) The intraluminal stent of claim 9, wherein the metallic reinforcing component and biodegradable polymeric material are provided within a laminated structure.

21. (Original) The intraluminal stent of claim 20, wherein the metallic reinforcing component is disposed between two or more layers of the biodegradable polymeric material.

22. (Original) The intraluminal stent of claim 21, wherein the two or more layers comprise different biodegradable polymeric materials.

23. (Previously presented) The intraluminal stent of claim 21, wherein at least one of said two or more layers comprises one or more therapeutic agents, one or more diagnostic agents, or a combination of one or more therapeutic agents and one or more diagnostic agents.

24. (Previously presented) The intraluminal stent of claim 23, wherein different therapeutic agents or different combinations of therapeutic agents are present in two or more of said layers.

25. (Original) The intraluminal stent of claim 21, wherein at least two of said layers have different rates of biodegradation.

26. (Previously presented) The intraluminal stent of claim 23, wherein at least two of said layers comprise a therapeutic agent and have different rates of release of the therapeutic agent therefrom.

27. (Original) The intraluminal stent of claim 1, wherein a surface of the metallic reinforcing component is passivated to enhance its biocompatibility.